THE POISON PREVENTION PACKAGING ACT OF 1970

DECEMBER 15, 1970.—Ordered to be printed

Mr. Staggers, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 2162]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 2162) to provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment insert the following:

Section 1. This Act may be cited as the "Poison Prevention Packaging Act of 1970".

SEC. 2. For the purpose of this Act—

(1) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(2) The term "household substance" means any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is-

(A) a hazardous substance as that term is defined in section 2(f) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f));

(B) an economic poison as that term is defined in section 2a of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.

(C) a food, drug, or cosmetic as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

(D) a substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.

(3) The term "package" means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household, and, for purposes of section 4(a) (2) of this Act, also means any outer container or wrapping used in the retail display of any such substance to consumers. Such term does not include-

(A) any shipping container or wrapping used solely for the transportation of any household substance in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail

distributors thereof, or

(B) any shipping container or outer wrapping used by retailers to ship or deliver any household substance to consumers unless it is

the only such container or wrapping.

(4) The term "special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

(5) The term "labeling" means all labels and other written, printed, or graphic matter (A) upon any household substance or its package, or (B)

accompanying such substance.

Sec. 3. (a) The Secretary, after consultation with the technical advisory committee provided for in section 6 of this Act, may establish in accordance with the provisions of this Act, by regulation, standards for the special

packaging of any household substance if he finds that-

(1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and

(2) the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance. (b) In establishing a standard under this section, the Secretary shall

consider-

(1) the reasonableness of such standard:

(2) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) the manufacturing practices of industries affected by his Act;

and

(4) the nature and use of the household substance.

(c) In carrying out this Act, the Secretary shall publish this findings, his reasons therefor, and citation of the sections of statutes which au-

thorize his action.

(d) Nothing in this Act shall authorize the Secretary to prescribe specific packaging designs, product content, package quantity, or, with the exception of authority granted in section 4(a)(2) of this Act, labeling. In the case of a household substance for which special packaging is required pursuant to a regulation under this section, the Secretary may in such regulation prohibit the packaging of such substance in packages which

he determines are unnecessarily attractive to children.

SEC. 4. (a) For the purpose of making any household substance which is subject to a standard established under section 3 readily available to elderly or handicapped persons unable to use such substance when packaged in compliance with such standard, the manufacturer or packer, as the case may be, may package any household substance, subject to such a standard, in packaging of a single size which does not comply with such standard if—

(1) the manufacturer (or packer) also supplies such substance

in packages which comply with such standard; and

(2) the packages of such substance which do not meet such standard bear conspicuous labeling stating: "This package for households without young children"; except that the Secretary may by regulation prescribe a substitute statement to the same effect for packaging too small to accommodate such labeling.

(b) In the case of a household substance which is subject to such a standard and which is dispensed pursuant to an order of a physician, dentist, or other licensed medical practitioner authorized to prescribe, such substance may be dispensed in noncomplying packages only when

directed in such order or when requested by the purchaser.

(c) In the case of a household substance subject to such a standard which is packaged under subsection (a) in a noncomplying package, if the Secretary determines that such substance is not also being supplied by a manufacturer (or packer) in popular size packages which comply with such standard, he may, after giving the manufacturer (or packer) an opportunity to comply with the purposes of this Act, by order require such substance to be packaged by such manufacturer (or packer) exclusively in special packaging complying with such standard if he finds, after opportunity for hearing, that such exclusive use of special packaging is necessary to accomplish the purposes of this Act.

Sec. 5. (a) Proceedings to issue, amend, or repeal a regulation prescribing a standard under section 3 shall be conducted in accordance with the procedures prescribed by section 553 (other than paragraph (3)(B) of the last sentence of subsection (b) of such section) of title 5 of the United States Code unless the Secretary elects the procedures prescribed by subsection (e) of section 701 of the Federal Food, Drug, and Cosmetic Act, in which event such subsection and subsections (f) and (g) of such section 701 shall apply to such proceedings. If the Secretary makes such election, he shall publish that fact with the proposal required to be published under

paragraph (1) of such subsection (e).

(b) (1) In the case of any standard prescribed by a regulation issued in accordance with section 553 of title 5 of the United States Code, any person who will be adversely affected by such a standard may, at any time prior to the 60th day after the regulation prescribing such standard is issued by the Secretary, file a petition with the United States Court of Appeals for the circuit in which such person resides or has his principal place of business for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the

record of the proceedings on which the Secretary based his standard, as

provided in section 2112 of title 28 of the United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there was no opportunity to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary in a hearing or in such other manner, and upon such terms and conditions, as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original standard, with the return of such additional evidence.

(3) Upon the filing of the petition under paragraph (1) of this subsection the court shall have jurisdiction to review the standard of the Secretary in accordance with subparagraphs (A), (B), (C), and (D) of paragraph (2) of section 706 of title 5 of the United States Code. If the court ordered additional evidence to be taken under paragraph (2) of this subsection, the court shall also review the Secretary's standard to determine if, on the basis of the entire record before the court pursuant to paragraphs (1) and (2) of this subsection, it is supported by substantial evidence. If the court finds the standard is not so supported, the court may set it aside.

(4) With respect to any standard reviewed under this subsection, the court may grant appropriate relief pending conclusion of the review

proceedings, as provided in section 705 of such title 5.

(5) The judgment of the court affirming or setting aside, in whole or in part, any such standard of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28 of the United States Code.

SEC. 6. (a) For the purpose of assisting in carrying out the purposes of this Act, the Secretary shall appoint a technical advisory committee, designating a member thereof to be chairman, composed of not more than eighteen members who are representative of (1) the Department of Health, Education, and Welfare, (2) the Department of Commerce, (3) manufacturers of household substances subject to this Act, (4) scientists with expertise related to this Act and licensed practitioners in the medical field, (5) consumers, and (6) manufacturers of packages and closures for household substances. The Secretary shall consult with the technical advisory committee in making findings and in establishing standards pursuant to this Act.

(b) Members of the technical advisory committee who are not regular full-time employees of the United States shall, while attending meetings of such committee, be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding \$100 per diem, including traveltime, and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for

persons in the Government service employed intermittently.

SEC. 7. (a) Section 2(p) of the Federal Hazardous Substances Act (15 U.S.C. 1261(p)) is amended—

(1) by striking out "which substance" in the part preceding paragraph (1) and inserting in lieu thereof "if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act

of 1970 or if such substance"; and

(2) by adding the following after and below paragraph (2): "The term 'misbranded hazardous substance' also includes a household substance as defined in section 2(2)(D) of the Poison Prevention Packaging Act of 1970 if it is a substance described in paragraph 1 of section 2(f) of this Act and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.".

(b) Section 2z(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(z)(2)) is amended by striking out the period at the end of paragraph (h) of such section and inserting in lieu thereof "; or"

and by adding at the end thereof a new paragraph as follows:

"(i) if its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(c) Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end thereof a new paragraph

as follows:

"(n) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(d) Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end thereof a new paragraph as

"(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(e) Section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(2)) is amended by striking out "and (h)" and insert-

ing in lieu thereof ", (h), and (p)"

(f) Section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362) is amended by adding at the end thereof a new paragraph as follows: "(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging

Act of 1970." SEC. 8. Whenever a standard established by the Secretary under this Act applicable to a household substance is in effect, no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the standard established under section 3 (and any exemption therefrom and requirement related thereto) of this Act.

SEC. 9. This Act shall take effect on the date of its enactment. Each regulation establishing a special packaging standard shall specify the date such standard is to take effect which date shall not be sooner than one hundred and eighty days or later than one year from the date such regulation is final, unless the Secretary, for good cause found, determines that an earlier effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier date shall apply. No such standard shall be effective as to household substances subject to this Act packaged prior to the effective date of such final regulation.

And the House agree to the same.

Harley O. Staggers,
John E. Moss,
John M. Murphy,
Hastings Keith,
Managers on the Part of the House.
Warren G. Magnuson,
Philip A. Hart,
Frank E. Moss,
James B. Pearson,
Charles E. Goodell,

Managers on the Part of the Senate.

STATEMENT OF THE MANAGERS ON THE PART OF THE HOUSE

The managers on the part of the House at the conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 2162) to provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, and for other purposes, submit the following statement in explanation of the effect of the action agreed upon by the conferees and recommended in the accompanying conference report:

The House amendment to the bill struck out all of the Senate bill after the enacting clause and inserted a substitute amendment. The committee of conference has agreed to a substitute for both the Senate bill and the House amendment to the bill. Except for technical, clarifying, and conforming changes, the following statement explains the differences between the House amendment and the substitute

agreed to in conference.

The conference substitute is identical to the bill as amended by the House except for the provision in section 4(a) authorizing manufacturers (or packers) of household substances subject to special packaging requirements to package such substances in packages not complying with such requirements for the purpose of making such substances readily available to the elderly and handicapped unable to use such substances in packages complying with such requirements.

In section 4(a), as amended by the House, the manufacturer (or packer) of a household substance subject to a special packaging requirement was given similar authority to package such a substance in noncomplying packages if he also packaged such substance in at least one package size complying with such standard and if the noncomplying packages were labeled to show that there were complying packages which should be used in households with young children. Thus, under the House version, most of the packages used in the marketing of such substances could be noncomplying packages. Complying packaging could have been the exception to general marketing practices.

Section 4(a) of the conference substitute is designed to make substances subject to special packaging requirements available to the elderly and handicapped in packages which do not unnecessarily hinder them in their use of such substances. A manufacturer (or packer) is permitted under such section to use for such a substance one size of packaging which does not meet the special packaging requirements if he also supplies the substance in packaging which complies with the requirements. In addition, the noncomplying packaging must be labeled to show it is not for households with young children.

It is expected that specially packaged substances will be the rule rather than the exception for substances regulated under this legislation. Also, it is expected that manufacturers (or packers) will not exact a premium price for specially packaged substances and will make every effort to assure the adequate distribution and advertisement of specially packaged substances so that the public will become acquainted with special packaging and familiar with its operation. Since the purpose of this section is to assist the elderly and handicapped, it is expected that the manufacturers (or packers) will use noncomplying packaging only when the required special packaging is of a kind that will create significant difficulty in use for the elderly and handicapped, and that manufacturers (or packers) will in using noncomplying packaging choose package sizes most likely to be used by the elderly and handicapped.

Although it has been pointed out that the majority of households do not contain young children, it was felt that, in order to adequately protect young children, the marketing in complying packaging of substances subject to special packaging requirements had to be made

the general marketing practice.

Section 4(b) of the conference substitute is identical to the House amendment and provides that in the case of household substances which are dispensed only upon prescription such substances (if subject to special packaging requirements) may be dispensed in noncomplying packages only when directed in the prescription or when requested

by the purchaser.

Section 4(c) of the conference substitute is the same as section 4(b) of the House version and authorizes the Secretary to require exclusive use of special packaging for substances if (1) he determines that the substance is not being supplied by the manufacturer (or packer) in popular sizes of special packages; and (2) after giving the manufacturer (or packer) an opportunity to comply with the purposes of this act, he finds, after opportunity for hearing, that exclusive use of special packaging is necessary to accomplish the purposes of this act.

The legislation as passed by the Senate contained a special provision (section 3(e)) authorizing the Secretary to exempt categories of substances subject to special packaging requirements. That special provision was not contained in the House version and is not contained in the conference substitute because the Secretary may provide such exemptions while prescribing such special packaging requirements. In addition, if the Secretary wishes to make such an exemption after he has prescribed special packaging requirements, he may use the informal rulemaking authority provided in section 5 of the conference substitute to amend the regulation prescribing such requirement.

Harley O. Staggers,
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